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Docket No: 10123/00701 (03-085)

REMARKS

Claims 11 and 15 have been cancelled. Claims 9, 10, 13, 14 and 16 have been amended to more particularly point out and distinctly claim the invention. No new matter has been added. Claims 1 - 10, 12 - 14 and 16 - 21 remain pending in the present application. In view of the above amendments and the following remarks, it is respectfully submitted that all of the pending claims are allowable.

Claims 1 - 7, 10, 12 - 14 and 16 - 17 stand rejected under 35 U.S.C. § 102(b) as anticipated by Firsch (U.S. Patent 4,447,237).

Claim 1 recites a pressure activated valve comprising "a flexible membrane disposed in the valve housing, the flexible membrane *including a slit extending therethrough so that the flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen.*"

Frisch describes an implantable shunt device 1 which includes a slit valve 20 which is opened only when a cannula-trocar assembly is inserted therethrough. (Specification, col. 5, ll. 8 - 20; Figs. 1 - 2.) The slit valve 20 remains closed at all times when the cannula-trocar assembly is not inserted therethrough -- regardless of the fluid pressure to which it is exposed -- and even when open seals around the cannula-trocar assembly to prevent flow around outside edges thereof. In fact, Frisch states that the functional requirements of shunt valving slits are "quite severe in that they must provide a positive seal when in a closed condition, which seal must remain effective during the entire period when the shunt device is implanted." (Specification, col. 2, lines 3 - 7). The valve slit must be capable of movement into the open condition from the closed condition "in response to the insertion of the cannular-trocar assembly." (Specification, col. 2, lines 18 - 20).

> [E]ach valving slit has, in addition to the bias provided by the elastomeric material of the body, additional means within the elastomeric material of the body for yieldingly biasing the opposed surfaces of the flattened sleeve into sealed relation when in the closed interengaged condition and into sealed relation to the exterior periphery of the portion of the cannula extending therethrough when in the open spaced apart condition.

Specification, col. 2, lines 41 - 50.

Thus, it is submitted that the valve of Frisch is designed to remain sealed at all times regardless of the fluid pressure applied thereto and opens only to permit the passage of a cannula therethrough. In fact, even when the cannula is inserted therethrough, the valve remains in a sealing relation around the cannula to prevent fluid from passing therearound through the slit. Therefore, it is therefore respectfully submitted that Frisch neither shows nor suggests a pressure activated valve comprising "a flexible membrane disposed in the valve housing, the flexible membrane including a slit extending therethrough so that *the flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen,*" as recited in claim 1. Because claims 2 - 7 depend from, and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable for at least the reasons stated above.

Claim 10 recites a dialysis catheter comprising a valve "comprising a flexible membrane with a slit extending therethrough wherein, *when a pressure above a predetermined threshold pressure is applied to the flexible membrane, the flexible membrane opens to allow a flow of blood through the slit.*" It is respectfully submitted that claim 10, as amended, is allowable for the same reasons stated above for claim 1. Because claims 12 and 13 depend from, and, therefore, include all of the limitations of claim 10, it is respectfully submitted that these claims are also allowable for at least the reasons stated above.

Claim 14, as amended, recites a medical device comprising a valve which "is *pressure*

activated to open when a fluid pressure within the lumen is at least a predetermined threshold value and remains sealed to prevent blood flow through the lumen when the fluid pressure within the lumen is below the predetermined threshold value." It is respectfully submitted that claim 14, as amended, is allowable for the same reasons stated above for claim 1. Because claims 16 and 17 depend from, and, therefore, include all of the limitations of claim 14, it is respectfully submitted that these claims are also allowable for at least the reasons stated above.

Claims 18 - 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by Steigerwald (U.S. Patent 5,009,391).

Claim 18 recites a pressure activated valve comprising "a flexible member disposed in the valve housing, the flexible member comprising *a plurality of flexible membranes stacked on one another*, each of the flexible membranes including at least one slit extending therethrough so that *each flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen*, wherein when all of the flexible membranes are moved to an open position, the flexible member is open to permit fluid flow through the housing

In contrast, Steigerwald describes a valve assembly which opens only when a catheter is slidably received therethrough. Similar to Frisch, the valve of Steigerwald does not open in response to fluid pressure within the lumen. "The inserted catheter 56 extends through the compression member 24, the port 42, the slits of the first and second valve member[s] 76 and 82 and through the sheath 50 into the vein." (Specification, col. 4, lines 6 - 9). "[T]he valve members 76 and 82 seal against the catheter 56 in order to prevent passage of air into the sheath 50, and prevent the passage of blood out through the valve members 76 and 82." (Specification, col. 4, lines 25 - 28). Thus, it is respectfully submitted that any opening of either of the valve members 76 and 82 due to fluid pressure is completely contrary to the purpose of the device of Steigerwald and is in no way shown or suggested by this patent. Because claims 19 - 21 depend from, and, therefore, include all of the limitations of claim 18, it is respectfully submitted that

these claims are also allowable for at least the reasons stated above.

Claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) as obvious over Frisch in view of Steigerwald. The Examiner stated, in support of the rejection, that Frisch shows the invention substantially as claimed except for the abutting flexible members but that this is shown by Steigerwald. However, as described above in regard to claims 1 and 18, neither Frisch nor Steigerwald either shows or suggests a pressure activated valve as recited in claim 1 (from which claims 8 and 9 depend). Thus, it is respectfully submitted that Steigerwald does not cure the above-noted defects of Frisch and claims 8 and 9 are allowable for the same reasons stated above in regard to claim 1.

Claims 19 and 20 stand rejected under 35 U.S.C. § 102(b) as obvious over Steigerwald in view of Frisch. The Examiner stated, in support of the rejection, that Steigerwald shows the invention substantially as claimed except for the non-thrombogenic coating but that this is shown by Frisch. However, as described above in regard to claims 1 and 18, neither Frisch nor Steigerwald either shows or suggests a pressure activated valve as recited in claim 18 (from which claims 19 and 20 depend). Thus, it is respectfully submitted that Frisch does not cure the above-noted defects of Steigerwald and claims 19 and 20 are allowable for the same reasons stated above in regard to claim 18.

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CONCLUSION

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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